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# NOTICE OF ALLOWANCE AND FEE(S) DUE

2292 7590 08/11/2008 BIRCH STEWART KOLASCH & BIRCH PO BOX 747 FALLS CHURCH, VA 22040-0747 EXAMINER

JARRELL, NOBLE E

ART UNIT PAPER NUMBER

DATE MAILED: 08/11/2008

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.	
10/565,105	01/19/2006	Yuzo Kakiya	0020-5462PUS1	5540	
TITLE OF INVENTION: PROCESS FOR PRODUCING IMIDE COMPOUND					

 APPLN TYPE
 SMALL ENTITY
 ISSUE FEE DUE
 PUBLICATION FEE DUE
 PREV. PAID ISSUE FEE
 TOTAL FEES) DUE
 DATE DUE

 nonprovisional
 NO
 \$1440
 \$300
 \$0
 \$1740
 11/12/2008

THE APPLICATION IDENTIFIED ABOVE HAS BEEN EXAMINED AND IS ALLOWED FOR ISSUANCE AS A PATENT. PROSECTION ON THE MERITS IS CLOSED. THIS NOTICE OF ALLOWANCE IS NOT A GRANT OF PATENT RIGHTS. THIS APPLICATION IS SUBJECT TO WITHDRAWAL FROM ISSUE AT THE INITIATIVE OF THE OFFICE OR UPON PETITION BY THE APPLICANT. SEE 37 CFR 1313 AND MPEP 1308.

THE ISSUE FEE AND PUBLICATION FEE (IF REQUIRED) MUST BE PAID WITHIN THREE MONTHS FROM THE MAILING DATE OF THIS NOTICE OR THIS APPLICATION SHALL BE REGARDED AS ABANDONED. THIS STATUTORY PERIOD CANNOT BE EXTENDED. SEE 35 U.S.C. 151. THE ISSUE FEE DUE INDICATED ABOVE DOES NOT REFLECT A CREDIT FOR ANY PREVIOUSLY PAID ISSUE FEE IN THIS APPLICATION. IF AN ISSUE FEE HAS PREVIOUSLY BEEN PAID IN THIS APPLICATION (AS SHOWN ABOVE), THE RETURN OF PART B OF THIS FORM WILL BE CONSIDERED A REQUEST TO REAPPLY THE PREVIOUSLY PAID ISSUE FEE TOWARD THE ISSUE FEE NOW DUE.

#### HOW TO REPLY TO THIS NOTICE:

I. Review the SMALL ENTITY status shown above.

If the SMALL ENTITY is shown as YES, verify your current SMALL ENTITY status:

A. If the status is the same, pay the TOTAL FEE(S) DUE shown above.

B. If the status above is to be removed, check box 5b on Part B Fee(s) Transmittal and pay the PUBLICATION FEE (if required) and twice the amount of the ISSUE FEE shown above, or

If the SMALL ENTITY is shown as NO:

A. Pay TOTAL FEE(S) DUE shown above, or

B. If applicant claimed SMALL ENTITY status before, or is now claiming SMALL ENTITY status, check box 5a on Part B - Fee(s) Transmittal and pay the PUBLICATION FEE (if required) and I/2 the ISSUE FFE shown above.

II. PART B - FEE(S) TRANSMITTAL, or its equivalent, must be completed and returned to the United States Patent and Trademark Office (USPTO) with your ISSUE FEE and PUBLICATION FEE (if required). If you are charging the fee(s) to your deposit account, section "4b" of Part B - Fee(s) Transmittal should be completed and an extra copy of the form should be submitted. If an equivalent of Part B is filed, a request to reapply a previously paid issue fee must be clearly made, and delays in processing may occur due to the difficulty in recognizing the paper as an equivalent of Part B.

III. All communications regarding this application must give the application number. Please direct all communications prior to issuance to Mail Stop ISSUE FEE unless advised to the contrary.

IMPORTANT REMINDER: Utility patents issuing on applications filed on or after Dec. 12, 1980 may require payment of maintenance fees. It is patentee's responsibility to ensure timely payment of maintenance fees when due.

#### PART B - FEE(S) TRANSMITTAL

# Complete and send this form, together with applicable fee(s), to: Mail Mail Stop ISSUE FEE Commissioner for Patents P.O. Box 1450 Alexandria, Virginia 22313-1450

or Fax (571)-273-2885

INSTRUCTIONS: This appropriate. All further condicated unless corrected maintenance fee notification	form should be used for correspondence including d below or directed oth ions.	or transm ig the Pat nerwise in	nitting the ISSU tent, advance on Block 1, by (a						tould be completed where correspondence address as rate "FEE ADDRESS" for
CURRENT CORRESPONDENCE ADDRESS (Note: Use Block I for any change of address)						Note: A certificate of mailing can only be used for domestic mailings of the Fee(s) Transmittal. This certificate cannot be used for any other accompanying papers. Each additional paper, such as an assignment or formal drawing, must have its own certificate of mailing or transmission.			
2292	7590 08/11	/2008						of Mailing or Transi	mission
BIRCH STEWART KOLASCH & BIRCH PO BOX 747 FALLS CHURCH, VA 22040-0747					I her State addr trans	eby certify that th	is Feet	() Transmittal is being	deposited with the United t class mail in an envelope above, or being facsimile tte indicated below.
									(Depositor's name)
					_				(Signature)
					L				(Date)
APPLICATION NO.	FILING DATE			FIRST NAMED INVENTOR			ATTO	RNEY DOCKET NO.	CONFIRMATION NO.
10/565,105	01/19/2006			Yuzo Kakiya			0	020-5462PUS1	5540
TITLE OF INVENTION:	PROCESS FOR PROD	OUCING I	IMIDE COMPO	UND					
APPLN. TYPE	SMALL ENTITY	ISSU.	E FEE DUE	PUBLICATION FEE D	UE.	PREV. PAID ISSU	FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	NO		\$1440	\$300		\$0		\$1740	11/12/2008
EXAMI	NER	Al	RT UNIT	CLASS-SUBCLASS					
JARRELL, 1	NOBLE E		1624	544-358000					
1. Change of correspondence address or indication of "Fee Address" (37 CFR 1.56).  Change of correspondence address (or Change of Correspondence Address form PTO/SB1/22) attached.  "Fee Address" indication or "Fee Address" indication form PTO/SB4/7, Rev 03-02 or more recent) attached. Use of a Custome Number is required.			orrespondence	2. For printing on the patent front page, list (1) the names of up to 3 registered patent attorneys or agents OR, alternativety, (2) the name of a single firm (having as a member a registered attorney or agent) and the names of up to 2 registered patent autorneys or agents. If no name is instel, no name will be printed.					
3. ASSIGNEE NAME AN PLEASE NOTE: Unle recordation as set forth (A) NAME OF ASSIG	ess an assignee is identi in 37 CFR 3.11. Comp				he pa	ntent. If an assign			scument has been filed for
Please check the appropria	ate assignee category or	categorie	es (will not be pr	inted on the patent):		Individual 🚨 Co	rporati	on or other private gro	up entity Government
4a. The following fee(s) are submitted:    Issue Fee   Publication Fee (No small entity discount permitted)   Advance Order - # of Copies				4b. Payment of Fee(s): (Please first reapply any previously paid issue fee shown above)  A check is enclosed.  Payment by redult cant. Form PTO-2038 is attached.  The Director is hereby authorized to charge the required fee(s), any deficiency, or credit any overspayment, to Deposit Account Number (enclose an extra copy of this form).					
	SMALL ENTITY statu	is. See 37						ITTY status. See 37 CI	
NOTE: The Issue Fee and interest as shown by the re	Publication Fee (if requeecords of the United Sta	uired) wil tes Patent	I not be accepted and Trademark	from anyone other the Office.	nan th	ne applicant; a regi	stered.	attorney or agent; or th	e assignee or other party in
Authorized Signature				Date					
Typed or printed name Registration No									
This collection of informa an application. Confidenti submitting the completed this form and/or suggestic Box 1450, Alexandria, Vi Alexandria, Virginia 2231	tion is required by 37 C iality is governed by 35 application form to the ons for reducing this bur rginia 22313-1450. DC 3-1450.	FR 1.311 U.S.C. 12 USPTO. rden, show NOT SE	. The informatic 22 and 37 CFR Time will vary ald be sent to the END FEES OR (	on is required to obtain 1.14. This collection is depending upon the e Chief Information O COMPLETED FORM	or n s esti indiv iffice S TC	etain a benefit by t imated to take 12 i idual case. Any co r, U.S. Patent and D'THIS ADDRESS	he pub minuter mment Trader i. SEN	tic which is to file (and to complete, includin s on the amount of tir nark Office, U.S. Deps D TO: Commissioner t	by the USPTO to process) g gathering, preparing, and ne you require to complete atment of Commerce, P.O. for Patents, P.O. Box 1450,

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BIRCH STEW	ART KO	JARRELL, NOBLE E			
PO BOX 747				ART UNIT	PAPER NUMBER
FALLS CHURCH, VA 22040-0747				1624	

DATE MAILED: 08/11/2008

# Determination of Patent Term Adjustment under 35 U.S.C. 154 (b)

(application filed on or after May 29, 2000)

The Patent Term Adjustment to date is 317 day(s). If the issue fee is paid on the date that is three months after the mailing date of this notice and the patent issues on the Tuesday before the date that is 28 weeks (six and a half months) after the mailing date of this notice, the Patent Term Adjustment will be 317 day(s).

If a Continued Prosecution Application (CPA) was filed in the above-identified application, the filing date that determines Patent Term Adjustment is the filing date of the most recent CPA.

Applicant will be able to obtain more detailed information by accessing the Patent Application Information Retrieval (PAIR) WEB site (http://pair.uspto.gov).

Any questions regarding the Patent Term Extension or Adjustment determination should be directed to the Office of Patent Legal Administration at (571)-272-7702. Questions relating to issue and publication fee payments should be directed to the Customer Service Center of the Office of Patent Publication at 1-(888)-786-0101 or (571)-272-4200.

# Notice of Allowability

Application No.	Applicant(s)
10/565,105	KAKIYA ET AL.
Examiner	Art Unit
Noble Jarrell	1624

2. ☑ The allowed claim(s) is/are 1 and 5. 3. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) ☐ All b) ☐ Some* c) ☐ None of the: 1. ☐ certified copies of the priority documents have been received. 2. ☐ Certified copies of the priority documents have been received in Application No 3. ☐ Copies of the certified copies of the priority documents have been received in Application No 3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)). *Certified copies not received:  Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.  THIS THREE-MONTH PERIOD IS NOT EXTENDABLE. 4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.  5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.  (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached  1) ☐ hereto or 2) ☐ to Paper No./Mail Date  (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date  (dentifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of sech sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.12(d).  6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BioLoGIGLAL MATERIAL must be submitted. Note the attached Examiner's comment regarding ReQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.  Attachment(s)  1. ☐ Notice of References Cited (PTO-892)  2. ☐ Notice of References Cited (PTO-892)  3. ☐ Information Disclosure State	— In MAILING DATE of this communication appears on to All claims being allowable, PROSECUTION ON THE MERTIS IS (OR REI- herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS. of the Office or upon petition by the applicant. See 37 CFR 1.313 and MP.	MAINS) CLOSED in this application. If not included appropriate communication will be mailed in due course. THIS This application is subject to withdrawal from issue at the initia
3.	<ol> <li>This communication is responsive to <u>amendment filed 4/30/08</u>.</li> </ol>	
a)   All   b)   Some* c)   None of the:  1.   Certified copies of the priority documents have been received. 2.   Certified copies of the priority documents have been received in Application No 3.   Copies of the certified copies of the priority documents have been received in Application No 3.   Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).  *Certified copies not received:  Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.  THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.  4.   A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.  5.   CORRECTED DRAWINGS (as "replacement sheets") must be submitted.  (a)   including changes required by the Notice of Draftsperson's Patent Drawing Review ( PTO-948) attached  1)   hereto or 2)   to Paper No./Mail Date  (b)   including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date  (dentifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be tabeled as such in the header according to 37 CFR 1.121(d).  6.   DEPOSIT OF and/or INFORMATION About the deposit of BioLogGIGAL MATERIAL.  Attachment(s)  1.   Notice of References Cited (PTO-992)  2.   Notice of References Cited (PTO-992)  3.   Information Disclosure Statements (PTO/SB/08), Paper No./Mail Date	<ol> <li>The allowed claim(s) is/are <u>1 and 5</u>.</li> </ol>	
THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.  4.  A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.  5.  CORRECTED DRAWINGS (as "replacement sheets") must be submitted.  (a)  including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached  1)  hereto or 2)  to Paper No./Mail Date	a) All b) Some* c) None of the:  1. Certified copies of the priority documents have been re  2. Certified copies of the priority documents have been re  3. Copies of the certified copies of the priority documents International Bureau (PCT Rule 17.2(a)).  * Certified copies not received:  Applicant has THREE MONTHS FROM THE "MAILING DATE" of this co	ceived.  ceived in Application No  have been received in this national stage application from the  sommunication to file a reply complying with the requirements
(a)	THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.  4. A SUBSTITUTE OATH OR DECLARATION must be submitted. Not	te the attached EXAMINER'S AMENDMENT or NOTICE OF
1. □ Notice of References Cited (PTO-892) 2. □ Notice of Draftperson's Patent Drawing Review (PTO-948) 3. □ Information Disclosure Statements (PTO/SB/08), Paper No./Mail Date Paper No./Mail Date Staminer's Amendment/Comment Paper No./Mail Date Staminer's Amendment/Comment 4. □ Examiner's Comment Regarding Requirement for Deposit of Biological Material	(a) \( \) including changes required by the Notice of Draftsperson's Pate 1) \( \) hereto or 2\( \) to Paper No./Mail Date \( \).  (b) \( \) including changes required by the attached Examiner's Amend Paper No./Mail Date \( \).  Identifying indicia such as the application number (see 37 CFR 1.84(c)) sheach sheet. Replacement sheet(s) should be labeled as such in the heade 6. \( \) DEPOSIT OF and/or INFORMATION about the deposit of Bit	ent Drawing Review ( PTO-948) attached  ment / Comment or in the Office action of  ould be written on the drawings in the front (not the back) of r according to 37 CFR 1.121(d).  DLOGICAL MATERIAL must be submitted. Note the
Q ☐ Other	4. Examiner's Comment Regarding Requirement for Deposit	6. ☐ Interview Summary (PTO-413), Paper No./Mail Date 7. ☐ Examiner's Amendment/Comment

/James O. Wilson/ Supervisory Patent Examiner Art Unit 1624

Page 2

Application/Control Number: 10/565,105

Art Unit: 1624

#### DETAILED ACTION

## Response to Arguments

- 1. The rejection under 35 U.S.C. 102 has been overcome by the amendment filed 4/30/08.
- The rejection under 35 U.S.C. 122, 2<sup>nd</sup> paragraph, has been overcome by the amendment filed 4/30/08.

### Allowable Subject Matter

- 3. Claims 1 and 5 are allowed.
- 4. The following is an examiner's statement of reasons for allowance: Saji et al. (US 5532372, issued July 2, 1996) is the closest prior art. Saji et al. teach the use of 13.7% HCl solution in acetone. In an affidavit provided, it has been shown that higher acetone impurities result from the use of a higher percent solution of HCl. This point is critical because if the impurities from acetone are too high, then the compound cannot be used in a drug formulation. In applicant's procedures, the impurities of acetone are at a level which still makes it safe to use the prepared compound as a drug. Thus, claims 1 and 5 are not anticipated or rendered obvious by Saji et al.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Noble Jarrell whose telephone number is (571) 272-9077. The examiner can normally be reached on M-F 7:30 A.M - 6:00 P.M. EST.

Application/Control Number: 10/565,105 Page 3

Art Unit: 1624

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. James O. Wilson can be reached on (571) 272-0661. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Noble Jarrell/ Examiner, Art Unit 1624 /James O. Wilson/ Supervisory Patent Examiner, Art Unit 1624